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Craig A. Slavin

PATENT

Applicant: Whayne et al.

Serial No.: 09/507,613

Filing Date: 02/21/00

Title: Catheter Distal Assembly
With Pull Wires

Group Art Unit: 3763

Examiner: Rodriguez

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**Attention: Board of Patent
Appeals and Interferences**

SECOND SUPPLEMENTAL APPEAL BRIEF

I. REAL PARTY IN INTEREST

The real party in interest in the present appeal is EP Technologies, Inc., the assignee of the present application. EP Technologies, Inc. is a wholly owned subsidiary of Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which will directly affect, or be directly affected by, or have a bearing on, the Board's decision in the present appeal.

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III. STATUS OF THE CLAIMS

Claims 10-37 are pending and are set forth in the Appendix (Exhibit 1). Claims 1-9 have been canceled. Claim 14 has been objected to. No claims have been allowed.

Claims 10-12, 15-23 and 27-37 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Pat. No. 6,071,279 to Whayne ("the Whayne '279 patent"). Claims 13 and 24-26 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Whayne '279 patent and U.S. Pat. No. 5,439,006 to Brennen ("the Brennen '006 patent").

Applicant appeals the rejection of claims 10-13 and 15-37.

IV. STATUS OF THE AMENDMENTS

No amendments were filed after the Final Office Action dated May 31, 2002, or after the Office Action dated May 12, 2003, which re-opened prosecution, or after the Office Action dated January 13, 2004, which re-opened prosecution for a second time.

V. SUMMARY OF THE INVENTIONS

Independent claim 10 is directed to a catheter assembly comprising a handle, an elongate catheter body and a control element. The handle includes a handle body and a ***strain relief element***. The elongate catheter body defines a distal portion, a proximal portion associated with the handle, and a size and flexibility suitable for insertion into a human body. The ***control element*** defines a distal portion operably connected to the distal portion of the catheter body and a ***proximal portion extending along the exterior surface of the catheter body***. The ***proximal portion*** of the control element is also ***secured to the strain relief element***. Claims 11-21 depend from independent claim 10 and include, *inter alia*, all of the limitations of claim 10.

One example of a catheter assembly in accordance with the invention defined by independent claim 10 is illustrated in Figure 42, a formal version of which is reproduced below. The exemplary catheter assembly 404 includes a catheter 12, a **handle 18 with a strain relief element 21**, and a pull wire 60 with a proximal portion that extends **along the exterior** of the catheter 12. The **proximal portion** of the pull wire 60 is also **secured to the handle's strain relief element 21** with an anchoring element 406.

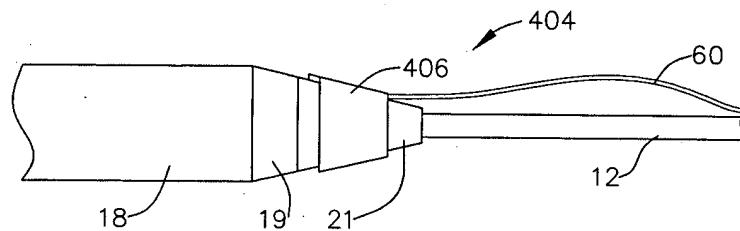


Figure 42 of the Present Application

Independent claim 22 is directed to a catheter assembly comprising a handle, an elongate catheter body, and a control element. The handle includes a handle body. The elongate catheter body defines a distal portion, a proximal portion associated with the handle, and a size and flexibility suitable for insertion into a human body. The control element defines a distal portion operably connected to the distal portion of the catheter body and a **proximal portion extending along the exterior surface of the catheter body**. The catheter assembly further comprises an **apparatus**, located in spaced relation to the handle body, that is **adapted to secure the proximal portion of the control element** in predetermined relation to **the catheter body**. Claims 23-37 depend from independent claim 22 and include, *inter alia*, all of the limitations of claim 22.

One example of a catheter assembly in accordance with the invention defined by independent claim 22 is illustrated in Figure 44, a formal version of which is reproduced on the following page. The exemplary catheter assembly 440 includes a catheter 12, a handle 18, and a pull wire 60 with a **proximal portion that extends along the exterior**

of the catheter 12. A gripping mechanism 422, which is located *in spaced relation to the handle 18*, secures the proximal portion of the pull wire 60 relative to the catheter 12.

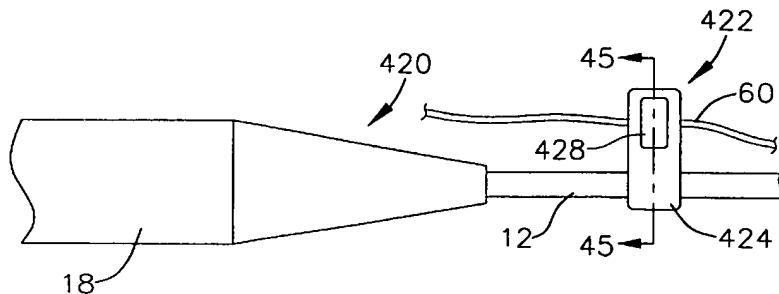


Figure 44 of the Present Application

VI. ISSUES

The present appeal presents the following two issues:

(1) whether, in accordance with 35 U.S.C. § 102, claims 10-12, 15-23 and 27-37 have been properly rejected as being anticipated by the Whayne '279 patent; and

(2) whether, in accordance with 35 U.S.C. § 103, claims 13 and 24-26 have been properly rejected as being unpatentable over the combined teachings of the Whayne '279 and Brennen '006 patents.

VII. GROUPING OF THE CLAIMS

Applicant respectfully submits that claims 10-21 are patentably distinct from claims 22-37. Accordingly, claims 10-21 stand or fall together and claims 22-37 stand or fall together.

VIII. ARGUMENTS

A. The Cited References

The Whayne '279 patent discloses a variety of catheter probes. As illustrated in Figure 1, which is reproduced below, catheter 10 includes a catheter tube 12 with a proximal end 14, which is connected to a handle 18, and a distal end 16, which is connected to an electrode structure 20. The catheter 10 also includes structures that allow the physician to deflect the catheter tube distal end 16. As described in column 11, lines 45-57 and illustrated in Figure 2A of the Whayne '279 patent, the catheter tube distal end 16 is connected by a steering wire 66 to a steering mechanism 68 (i.e. a rotatable knob) on the handle 18. Rotation of the steering mechanism 68 causes the steering wire 66 to deflect the catheter tube distal end 16.

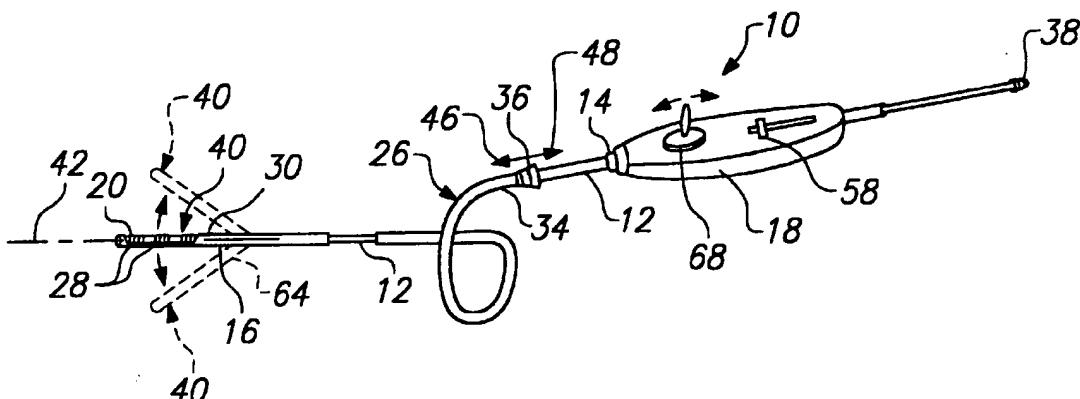


Figure 1 of the Whayne '279 Patent

The catheter 10 includes a sheath 34 with a gripping surface 36. During use, the catheter tube 12 is located within the sheath 34 and is slideable relative to the sheath in the directions represented by arrows 46 and 48. [Column 9, lines 6-40.]

Turning to Figures 51 and 53, which are reproduced in the following page, the Whayne '279 patent also discloses probes with an operative branch 274 that may be passed through the catheter tube 12 until it exits the catheter tube distal end 16 by way of

a slot 320. Referring more specifically to Figure 53 and column 27, line 66 to column 28, line 15, the branch 274 may be pulled into a loop with a pull wire 334. The pull wire 334 extends to through a sheath 304 to an accessible stop 336. The Whayne '279 patent describes "stops" as devices that are *held by the physician* while forming the loop. [Column 14, lines 54-61.]

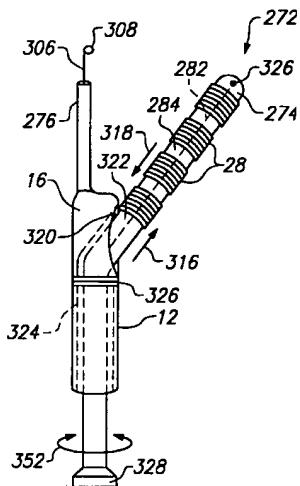


FIG. 51

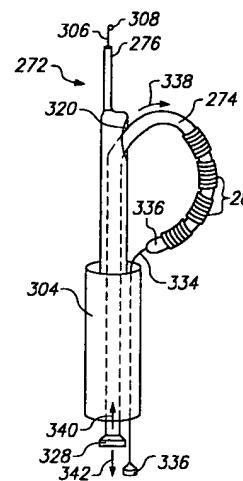


FIG. 53

Figures 51 and 53 of the Whayne '279 Patent

Referring to Figure 1, which is reproduced below, the Brennen '006 patent discloses a steerable device including a tubular member 10, a pull wire 12 with a proximal section 14 and a distal section 16, and a handle 28. The handle 28 includes a pivotable lever that is used to pull the pull wire 12 in response to sliding movement of a slidable member 32. [Column 7, lines 16-49.]

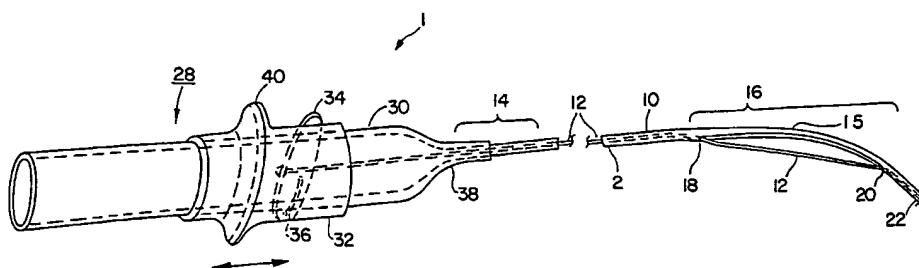


Figure 1 of the Brennen '006 Patent

B. The Present Application Claims Priority to an Application With an Essentially Identical Disclosure as, and the Same Priority Date as, the Whayne '279 Patent

As discussed in greater detail in Sections VIII-C and VIII-D below, it is applicant's position that the rejection of claims 10-12, 15-23 and 27-37 under 35 U.S.C. 102(e) is improper because the claims are not anticipated by the Whayne '279 patent. Nevertheless, and the impropriety of the rejection under 35 U.S.C. 102 notwithstanding, the Office Action appears to be taking the following two seemingly contradictory positions: (1) that the Whayne '279 patent anticipates claims 10-12, 15-23 and 27-37 because it discloses each and every element of each of the claims, and (2) that the earliest application to which the present application claims priority does not support the subject matter defined by claims 10-12, 15-23 and 27-37 despite the fact that the disclosure of the **earliest priority application is essentially identical** to that of the Whayne '279 patent. The issues raised by this aspect of the Office Action are discussed below.

1. Background Information

The Whayne '279 patent is based on U.S. application Serial No. 08/771,217, which was filed on **December 19, 1996** ("the Whayne '217 application"). The present application is a continuation of U.S. application Serial No. 08/961,374, which was itself a continuation-in-part of U.S. application Serial No. 08/769,856 ("the Yang '856 application"). The Yang '856 application, which is incorporated by reference into the present application, was filed on **December 19, 1996** and issued as U.S. Patent No. 6,332,880 ("the Yang '880 patent").¹

Turning to the outstanding rejection under 35 U.S.C. § 102(e), the drawings and "detailed description of the preferred embodiments" portions of the specifications were essentially identical in the Whayne '217 application and the Yang '856 application. For

¹ The Yang '880 patent is of record in the present application.

example, as shown in the chart below, the portions of the Whayne '279 patent identified in the outstanding Office Action are identically present in the Yang '880 patent.

The Whayne '279 Patent	The Yang '880 Patent
Figures 1 and 53	Figures 1 and 53
Column 11, lines 45-57; and column 27, line 66 to column 28, line 15.	Column 11, lines 33-45; and column 27, line 57 to column 28, line 6.

2. The Examiner's Statement Concerning Priority

In support of the decision to deny claims 10-12, 15-23 and 27-37 the benefit of the earliest priority application, the Office Action includes the following statement:

Please note that applicant is getting the effective filing date of Patent No. 6,203,525, filed on October 30, 1997 and not from Patent No. 6,332,880, since Patent ('525) is a C-I-P of ('880). The current application and patent ('525) contain new claimed subject matter that is not disclosed in ('880).

[Office Action at page 2.] It is not entirely clear what information the Examiner was attempting to convey with this statement. However, it appears that the Examiner has taken the position that because *some* of the claims in the present application are directed to subject matter that was not disclosed in the earliest priority application, *none* of the claims are entitled to the filing date of the earliest priority application. This is, of course, entirely incorrect. "A C-I-P application can be entitled to different priority dates for different claims. Claims containing any matter introduced in the C-I-P are accorded the filing date of the C-I-P application. However, *matter disclosed in the parent application is entitled to the benefit of the filing date of the parent application.*" *Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994), citations omitted, emphasis added.

There are six (6) conditions for receiving the benefit of an earlier filed application under 35 U.S.C. § 120 outlined in MPEP § 201.11. The Office Action does not even assert, let alone prove, that any of claims 10-12, 15-23 and 27-37 fail to meet the conditions for receiving the benefit of the earliest priority application (i.e. the Yang '856

application/Yang '880 patent) when the language of the claims is interpreted in the manner proposed in the Office Action.

3. Conclusion

The merits of the rejection notwithstanding, to the extent that the Whayne '279 patent anticipates claims 10-12, 15-23 and 27-37 under 35 U.S.C. § 102(e), the Examiner has failed to show that claims 10-12, 15-23 and 27-37 are not entitled to priority to the December 19, 1996 filing date of the Yang '856 application under 35 U.S.C. § 120. Given that the effective filing dates of claims 10-12, 15-23 and 27-37 and the Whayne '279 patent would then be the same, the Whayne '279 patent is not prior art with respect to claims 10-12, 15-23 and 27-37 under 35 U.S.C. § 102(e).² The rejection of claims 10-12, 15-23 and 27-37 under 35 U.S.C. § 102(e) is, therefore, improper and must be reversed.

C. Claim Interpretation Issues Raised by the Office Action

The Examiner has taken the position that the rotatable steering mechanism 68 and/or the stop 336 disclosed in the Whayne '279 patent is/are a "strain relief element." [Office Action at page 2.] Whether the Examiner intended to indicate that the rotatable steering mechanism 68 is a "strain relief element," that the stop 336 is a "strain relief element," or that some combination of the rotatable steering mechanism 68 and stop 336 is a "strain relief element," the Examiner's interpretation of the phrase "strain relief element" is unreasonable because (1) it is inconsistent with the specification of the present application and (2) it is inconsistent with the meaning ascribed to the term "strain relief" by those of skill in the art.

² 35 U.S.C. § 102(e) requires that the claimed invention be "described in a patent granted on an application for patent by another filed in the United States **before** the invention thereof by the applicant."

1. The Legal Standard

Claims in an application are to be given their broadest reasonable interpretation. This interpretation must be “consistent with the specification” and “consistent with the one that those skilled in the art would reach.” *In re Cortright*, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999). One way to determine the interpretation which one of skill in the art would ascribe to a particular term is to review analogous prior art references. *Vitronics Corp. v. Conceptronic, Inc.*, 39 USPQ2d 1573, 1578-79 (Fed. Cir. 1996) (“prior art can often help to demonstrate how a disputed term is used by those skilled in the art”). As such, “the PTO’s interpretation of claim terms should not be so broad that it conflicts with the meaning given to identical terms in other patents from analogous art.” *In re Cortright*, 49 USPQ2d at 1467.

2. The Present Specification

With respect to the present specification, “strain relief elements” were notoriously well known devices at the time the present application was filed. “Strain relief elements” were, at the time the present application was filed, used to reduce the mechanical strain on the proximal portion of a catheter when the catheter is bent relative to a handle or other structure. For this reason, the present application did not go to great lengths to explain what a “strain relief element” is.³ The specification identifies one example of a “strain relief element” as being represented by reference numeral 21 in Figures 41 and 42. [A formal version of Figure 42 is reproduced on the following page.] Figures 41 and 42 present the strain relief element 21 as a structure that is associated with the handle 18 and the proximal end of the catheter tube 12.

³ “[A] patent need not teach, and preferably omits, what is well known in the art.” *Hybritech Incorporated v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986).

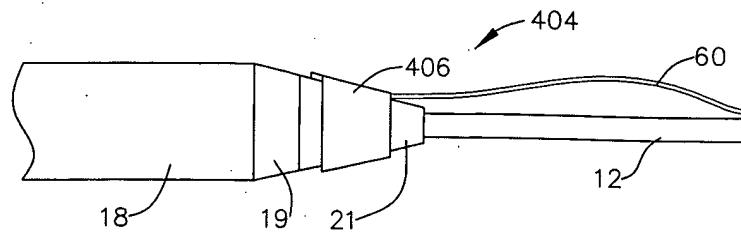


Figure 42 of the Present Application

The present application also discusses the use of rotatable steering mechanisms and stops in the context of **other catheters**. This discussion is important in the context of the outstanding rejections because it shows that the present specification uses the terms "steering mechanism" and "stop," in exactly the same manner as the Whayne '279 patent, to refer to something other than a "strain relief element."

Some of these catheters include steering wires and rotatable steering mechanisms that are used to pull the steering wires. Referring to Figure 1, a formal version of which is reproduced below, the present application discloses a catheter 10 with a catheter tube 12 and a handle 18. The catheter 10 also includes structures that allow the physician to deflect the distal portion of the catheter tube 12. As described on page 16, lines 1-10, the distal region of the catheter tube 12 is connected by a steering wire 96 to a steering mechanism 98 (i.e. a rotatable knob) on the handle 18. Rotation of the steering mechanism 98 pulls on the steering wire 96 and causes the steering wire to deflect the distal region of the catheter tube 12. In other words, the present application uses the phrase "steering mechanism" to refer to exactly the same structural element as the Whayne '279 patent, i.e. a rotatable device that is used to manipulate steering wires.

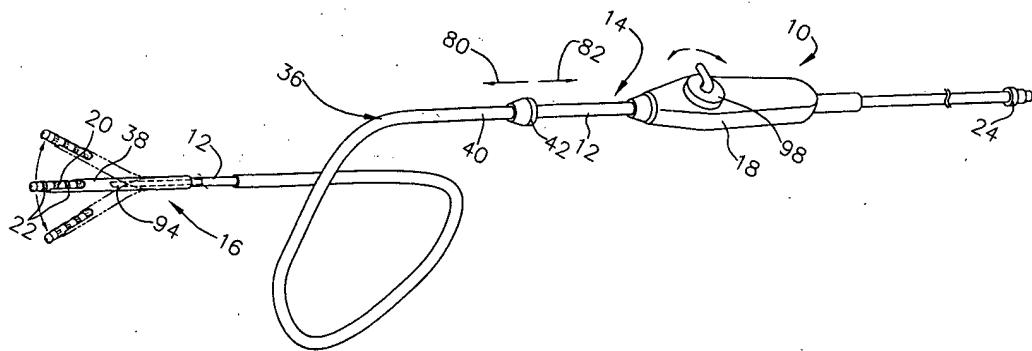


Figure 1 of the Present Application

Turning to Figure 3A, a formal version of which is reproduced below, the present application also discloses a catheter which includes a pull wire 60 that extends through the sheath 36 to a stop 62. [Page 13, lines 15-26.] The stop 62 is held by the physician, thereby fixing the position of the pull wire 60, during the loop formation process. In other words, the present application uses the phrase "stop" to refer to exactly the same structural element as the Whayne '279 patent, i.e. a device that is held by the physician during the loop formation process to fix the position of the pull wire.

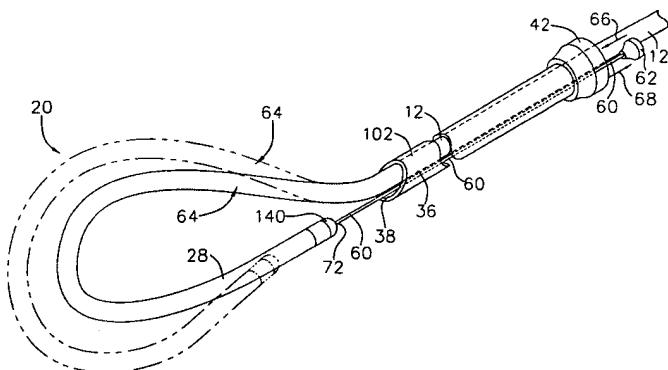


Figure 3A of the Present Application

As illustrated above, the present specification makes it perfectly clear that a "strain relief element" and a rotatable "steering mechanism" are two entirely different things. The present specification also makes it perfectly clear that a "strain relief element" and a "stop" are two entirely different things. The Examiner's interpretation of the phrase "strain relief element" (i.e. that it corresponds to a rotatable steering mechanism, a stop, or some combination thereof) is, therefore, inconsistent with the present specification and, for this reason alone, unreasonable.

3. The Skilled Artisan

The Examiner's interpretation of the phrase "strain relief element" also conflicts with the interpretation that those skilled in the art would reach. To that end, attached hereto are five analogous prior art references from the catheter art. Each of the catheter

references uses the phrase "strain relief" in the same manner as the present specification.

U.S. Patent No. 4,583,968 to Mahurkar ("the Mahurkar '968 patent") is attached hereto as Exhibit 2. Referring to Figure 1, which is reproduced below, the Mahurkar '968 patent includes the following passage in column 3, lines 31-35:

The branching connector 15 includes a coaxial sleeve 15' at the junction of the tube 11 and the connector 15. The sleeve 15' acts as a **strain relief** and also prevents kinking of the tube 11 at the junction. [Emphasis added.]

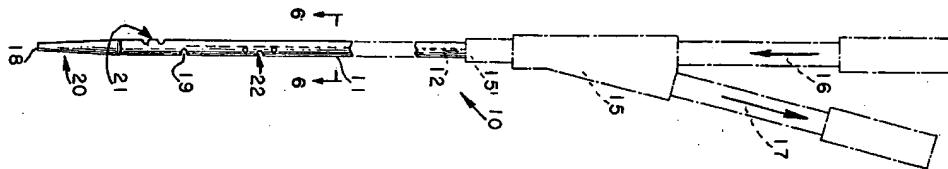


Figure 1 of the Mahurkar '968 Patent (rotated)

U.S. Patent No. 5,167,647 to Wijkamp ("the Wijkamp '647 patent") is attached hereto as Exhibit 3. Referring to Figure 1, which is reproduced below, the Wijkamp '647 patent includes the following passage in column 2, lines 43-50:

A **strain relief** tube 5 is pushed over the proximal end portion of the tubular body 2, while strain relief tube 5 is secured in an aperture in the coupling element 6. Strain relief member 5 serves to **reinforce the catheter** at that location. [Emphasis added.]

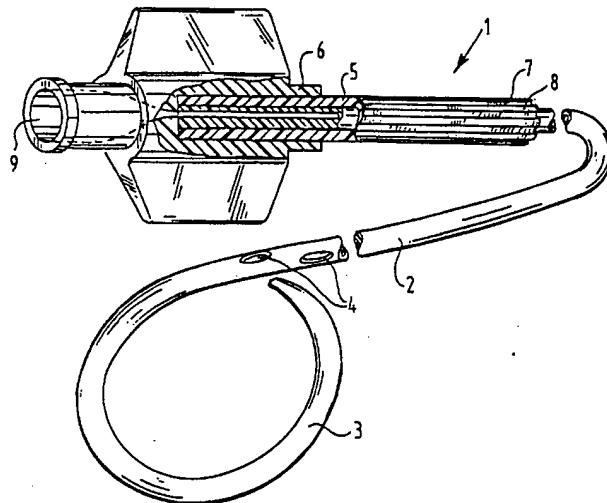


Figure 1 of the Wijkamp '647 Patent

U.S. Patent No. 5,499,981 to Kordis ("the Kordis '981 patent") is attached hereto as Exhibit 4. With reference to Figure 55, which is reproduced below, the Kordis '981 patent states that "a **strain relief** 163 surrounds the junction of the proximal catheter tube 14 with the handle 18." [Column 15, lines 29-31, emphasis added.]

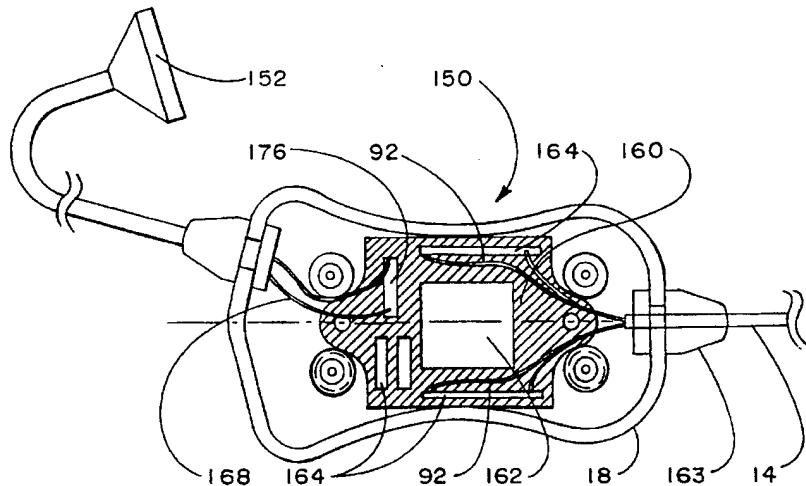


Figure 55 of the Kordis '981 Patent

U.S. Patent No. 5,507,995 to Schweich ("the Schweich '995 patent") is attached hereto as Exhibit 5. With reference to Figure 1, which is reproduced below, the Schweich '995 patent includes the following passage in column 6, lines 58-61:

Located on a distal end of the manifold 78 and extending along the proximal end of the elongate shaft 9 is a **strain relief** 86. The strain relief 86 is made of a relatively flexible plastic material. [Emphasis added.]

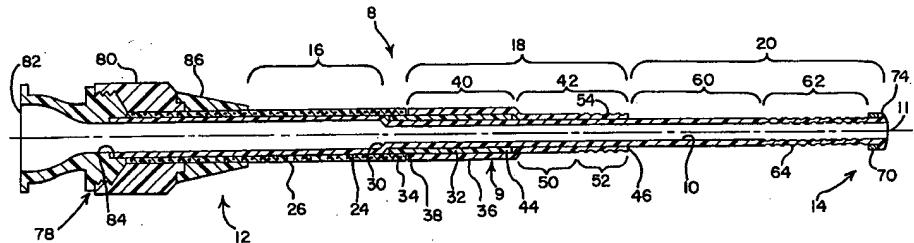


Figure 1 of the Schweich '995 Patent

U.S. Patent No. 5,527,325 to Conley ("the Conley '325 patent") is attached hereto as Exhibit 6. Referring to Figure 1, which is reproduced on the following page, the Conley

'325 patent states that the "proximal assembly 50 includes a distal ***strain relief*** 52 at the point where catheter body 22 joins proximal assembly 50." [Column 12, lines 52-54, emphasis added.]

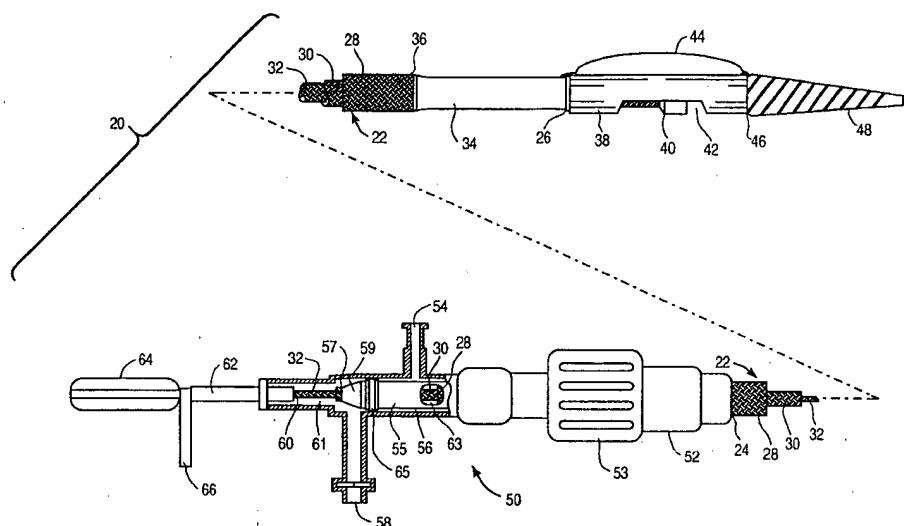


Figure 1 of the Conley '325 Patent

As exemplified by five analogous patents, one of ordinary skill in the catheter art would understand the phrase "strain relief element" to be a reference to a device that is associated with a handle and that is used to reduce mechanical strains on the proximal portion of the catheter. The Examiner's interpretation is, therefore, also in conflict the meaning given to the phrase "strain relief" in other patents from analogous art.

4. The Examiner's Definition

Despite the unambiguous language used by the Federal Circuit to describe what is meant by the phrase “broadest reasonable interpretation,” the teachings of the present specification and drawings, and the teachings of five analogous patents, the Examiner has taken it upon himself to cobble together his own definition of the term “strain relief element” based on the separate definitions of the terms “strain” and “relief” in the *American Heritage Dictionary of the English Language, Third Edition* (1992). The Examiner apparently relied on *In re Morris*, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997), to justify this action. Applicant respectfully submits that the Examiner’s reliance on *In re*

Morris is misplaced, and resulting definition of “strain relief element” is simply wrong, for a variety of reasons.

For example, in *In re Morris*, the court held that interpreting the phrase “integrally formed as a portion of” to cover more than “a unitary construction” was reasonable because the USPTO was able to support its position with ***numerous CCPA decisions*** that supported its interpretation. ***The present Examiner***, on the other hand, ***has not provided anything*** – not a CCPA decision, not a Federal Circuit decision, not a Board of Appeals decision, not a patent from the catheter art, not a technical paper from the catheter art – to support the interpretation set forth in the Office Action. The absence of evidence from the Examiner stands in stark contrast to the abundance of evidence provided by applicant as to what the interpretation should be, i.e. a device that is associated with a handle and used to reduce mechanical strains on the proximal portion of the catheter body.

The Examiner also quoted the portion of the *In re Morris* decision which states that “the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment ***by way of definitions*** or otherwise ***that may be afforded by the written description contained in the applicant's specification.***” *Id.* at 1027, *emphasis added*. The Examiner even underlined the word “definitions.” [Office Action at page 6.] Unfortunately, the Examiner appears to have ignored the “that may be afforded by the written description contained in applicant's specification” portion of this statement.⁴ The Examiner also appears to have ignored the beginning of the sentence that he is quoting. The beginning of the sentence reads “[s]ince it would be unreasonable for the PTO to ignore any interpretive guidance afforded by the ***applicant's written description ...***” *Id.*, *emphasis added*. Accordingly, the Examiner has ignored the fact that the portion of *In re Morris* decision

⁴ The reference to “applicant’s specification” in the *In re Morris* decision was brought to the Examiner’s attention in the Supplemental Appeal Brief filed on October 7, 2003. Not only has the Examiner failed to address this issue, based on the most recent Office Action it would appear that the Examiner has also refused to so much as read the case that he is citing for authority.

cited in the Office Action mandates that, absent persuasive authority to the contrary, the PTO must apply claim language in the manner the applicant's specification and the manner in which those of skill would apply it. As discussed above in Section VIII-C-2, applicant's specification does not in any way support the Examiner's interpretation of the term "strain relief element" and, in fact, clearly shows that a "strain relief element" is something entirely different than a rotatable steering mechanism or a stop.

Finally, with respect to the so-called "support" cobbled together by the Examiner from the separate dictionary definitions of the words "strain" and "relief" found in the *American Heritage Dictionary* (Office Action at page 6), the Federal Circuit has repeatedly warned against using non-scientific dictionaries to define technical terms of art. For example, in *AFG Industries Inc. v. Cardinal IG Co.*, 57 USPQ2d 1776, 1783 (Fed. Cir. 2001), the Federal Circuit stated:

This court has repeatedly cautioned against using non-scientific dictionaries for defining technical words ... Dictionary definitions of ordinary words are **rarely dispositive** of their meanings in a technological context. A word describing patented technology **takes its definition from the context** in which it was used by the inventor..... **A general definition is secondary to the specific meaning of a technical term as it is used and understood in a particular technical field.**

[Citations omitted, emphasis added.] Thus, although dictionary definitions may be useful in determining the meaning of non-technical words such as "portion," they are inapplicable to a term such as "strain relief element" which has a clearly defined meaning in the catheter art.

5. The Examiner's Failure to Address the Issues Raised by the Analogous Patents Cited Above

Applicant advised the Examiner that his interpretation of the phrase "strain relief element" conflicts with the meaning given to the phrase "strain relief" in five analogous patents in the Response to the Final Office Action filed on July 30, 2002 ("the July 30, 2002 response"). The Examiner failed to discuss these patents in the Advisory dated September 18, 2002 ("the September 18, 2002 Advisory Action") and, instead, presented

applicant with a mish-mash of case citations CCPA and CAFC that either supported applicant's arguments or had little to do with the issues in the present application.

In response to the September 18, 2002 Advisory Action, applicant again advised the Examiner that his interpretation of the phrase "strain relief element" conflicts with the meaning given to the phrase "strain relief" in five analogous patents. [See pages 8-11 of the Appeal Brief filed on February 14, 2003 ("the February 14, 2003 Appeal Brief").] The Examiner responded to the February 14, 2003 Appeal Brief with an Office Action that reopened prosecution ("the May 12, 2003 Office Action"). Here, the Examiner again failed to address the fact that his interpretation of the phrase "strain relief element" conflicts with the meaning given to the phrase "strain relief" in five analogous patents. Instead, the Examiner took the word "definitions" out of the context in which it is used in the *In re Morris* case, and cobbled together a definition of the phrase "strain relief element" that conflicts with the meaning given to the phrase "strain relief" in the five analogous patents.

In response to the reopening of prosecution by way of the May 12, 2003 Office Action, applicant advised the Examiner for **a third time** that his interpretation of the phrase "strain relief element" conflicts with the meaning given to the phrase "strain relief" in five analogous patents. [See pages 11-14 of the Supplemental Appeal Brief filed on October 7, 2003 ("the October 7, 2003 Appeal Brief").] The Examiner responded to the October 7, 2003 Appeal Brief with an Office Action that reopened prosecution for a second time ("the January 13, 2004 Office Action"). Here again, the Examiner failed to address the fact that his interpretation of the phrase "strain relief element" conflicts with the meaning given to the phrase "strain relief" in five analogous patents. The Examiner also failed to respond to the fact that he has misapplied the *In re Morris* case and taken certain language contained therein out of context.

Finally, in the October 7, 2003 Appeal Brief, applicant also raised the issue of the Examiner's use of a non-scientific dictionary to define technical terms of art in such a manner that the definition conflicts with meaning ascribed to the technical term by those of skill in the art. Other than mis-quoting the *In re Morris* decision, the Examiner has not replied to applicant's arguments.

6. The “Special Meaning” Issue

In the most recent Office Action, the Examiner invented a new reason for ignoring the law concerning claim interpretation and the factual evidence presented by applicant concerning the meaning that those of skill in the art would ascribe to term “strain relief element.” The new reason appears to be the “special meaning” requirement, which the Examiner described as follows:

[i]t would not be proper for the examiner to give words of the claim special meaning when no such meaning has been defined by the applicant in the written description.

[Office Action at page 6.] In other words, the present Examiner has apparently taken the position that if an applicant desires the examiner assigned to his/her application to interpret words and phrases in the manner that they are already interpreted by those of skill in the art (i.e. be given a “special meaning”), applicant must provide specific definitions of those words and phrases in the text of the application. This new requirement would apparently extend to each and every element discussed in the specification that applicant may at some point desire to refer to in the claims, no matter how well known these elements are to those of skill in the art.

Applicant respectfully submits that the U.S. patent laws and rules, as interpreted by the United States Court of Appeals for the Federal Circuit, do not include the Examiner’s “special meaning” requirement. To the contrary, as noted above, claim interpretation **must be** “consistent with the specification” and “consistent with the one that those skilled in the art would reach” and **must not** “be so broad that it conflicts with the meaning given to identical terms in other patents from analogous art.” *In re Cortright*, 49 USPQ2d at 1467. The Examiner’s interpretation fails all three tests – it is inconsistent with the specification, it is inconsistent with the interpretation of those of skill in the art, and it conflicts with the meaning given to identical terms in analogous patents. Additionally, as also noted above, “a patent need not teach, and **preferably omits**, what is well known in the art.” *Hybritech Incorporated v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986), *emphasis added*. Accordingly, applicant respectfully submits that the

Examiner's "special meaning" requirement is improper and has no place in the interpretation of applicant's claims.

Finally, to the extent that the Examiner has raised the "special meaning" issue in the "applicant can be his own lexicographer" context (see, e.g. MPEP § 2111.01), applicant respectfully submits that this is also improper. The use of the phrase "strain relief element" in the present application *is not* a "departure from common usage" that must "be so understood by a person of experience in the field of the invention." MPEP § 2111.01, quoting *Multiform Desiccants Inc. v. Medzam Ltd.*, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). To the contrary, the use of the phrase "strain relief element" in the present application *is the common usage* in the art.

7. Other Erroneous Statements Associated With The Claim Interpretation Issues

Finally, for reasons that are not entirely clear to applicant, page 7 of the January 13, 2004 Office Action that reopened prosecution for a second time includes the following statement:

The phrase "strain relief element" is a descriptive word [sic] and does not impart an specific structure (in the claims) since it has not being [sic] well described structurally and functionally in the claims with respect and in combination to [sic] the other elements.

To the extent that the Examiner intended to suggest that the term "strain relief element" is somehow entitled to less patentable weight than it would be if it was re-characterized in some other way, the Examiner's statement is respectfully traversed. Applicant has chosen to use a term (i.e. "strain relief element") that is well understood by those of skill in the art generally and, more specifically, is understood by those of skill in the art to mean something other than a rotatable steering knob or a stop that is held by the physician during loop formation, as has been incorrectly asserted by the Examiner. The U.S. patent laws and rules require no more.

8. Conclusion

In view of the foregoing, applicant respectfully submits that the Examiner's interpretation of the phrase "strain relief element" is unreasonable because it is inconsistent with the specification, is inconsistent with the one that those skilled in the art would reach and is in conflict with analogous patents. As illustrated in Figure 42 of the present application, and as discussed in five prior patents, a "strain relief element" is a device that reduces the mechanical strains on the proximal portion of a catheter as the catheter is bent relative to a handle or other structure. The Examiner's hypothesis concerning strain on a steering wire notwithstanding, a "strain relief element" simply is not a rotatable steering knob or a stop that is held by the physician during loop formation.

D. Discussion Concerning Claims 10-13 and 15-21 and the Cited References

Independent claim 10 calls for a combination of elements comprising "*a handle including* a handle body and a *strain relief element*," "an elongate catheter body ... associated with the handle" and "*a control element* defining a distal portion operably connected to the distal portion of the catheter body and a proximal portion extending along the exterior surface of the catheter body and *secured to the strain relief element*."

1. The Rejection of Claims 10-12 and 15-21 Under 35 U.S.C. § 102

Applicant respectfully submits that the Whayne '279 patent fails teach or suggest a number of elements in the combination defined by independent claim 10. For example, the Whayne '279 patent fails to teach or suggest the use of a "strain relief element." The text of the Whayne '279 patent does not even include the word "strain" or the word "relief." The Examiner has, nevertheless, taken the position that the rotatable steering element 68 in Figure 1 and/or the stop 336 of the Whayne '279 patent corresponds to the claimed "strain relief element." Such an interpretation is unreasonable because it (1) is

inconsistent with the specification and (2) is inconsistent with the interpretation that those skilled in the art would reach. [See the discussion in Section VIII-C on pages 8-16 above.] For this reason alone, the rejection of claims 10-12 and 15-21 under 35 U.S.C. § 102 is improper and should be reversed.

The Whayne '279 patent also fails to teach or suggest other aspects of the claimed combination. Referring first to Figure 1, the rotatable steering element 68 is connected to a steering wire 66 that is located **within** the catheter tube 12. As such, the Whayne steering element 68 is not connected to "a control element defining ... a proximal portion extending along the **exterior surface** of the catheter body," as called for in the combination defined by independent claim 10.

Turning to the structure illustrated in Figure 53 of the Whayne '279 patent, the combination defined by independent claim 10 calls for "a handle including ... a strain relief element." The Office Action appears to have taken the position that the Whayne catheter tube 12 and branch structure 274 together correspond to the claimed "catheter body." Even assuming *arguendo* that this is the case, the pull wire 334 is secured to the stop 336 and, notwithstanding the fact that the stop 336 is not a "strain relief element," there is nothing in the Whayne '279 patent which indicates that the handle 18 **includes** the stop 336. [Note that the Whayne '279 patent describes stops as devices that must be held by the physician during loop deployment.]

As the Whayne '279 patent fails to teach or suggest each and every element of the combination recited in independent claim 10, applicant respectfully submits that claims 10-12 and 15-21 are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and must be reversed.

2. The Rejection of Claim 13 Under 35 U.S.C. § 103

The Brennen '006 patent, which was cited with respect to dependent claim 13, fails to remedy the deficiencies in the Whayne '279 patent described above with respect to independent claim 10. For example, the Brennen patent does not teach or suggest the use of a "strain relief element." The Examiner has taken the position that the

pivotal lever 34, which is used to pull the pull wire 12, is a “strain relief element.” As discussed in Section VIII-C in the context of the Whayne rotatable steering element 68 (pages 8-16 above), such an interpretation is unreasonable because it is inconsistent with the specification and is inconsistent with the interpretation that those skilled in the art would reach.

The Brennen patent also fails to teach or suggest “a control element defining … a **proximal portion** extending along the **exterior** surface of the catheter body and secured to the strain relief element.” The proximal section 14 of the Brennen pull wire 12 is clearly located **within the interior** of the tubular member 10. As such, the Brennen patent adds nothing to the Whayne steering wire 66 and rotatable steering element 68 arrangement.

As the Whayne ‘279 and Brennen ‘006 patents fail to teach or suggest the combination of elements recited in claim 13 (which by definition includes the combination of elements recited in independent claim 10), applicant respectfully submits that the rejection of claim 13 under 35 U.S.C. § 103 is improper and must be reversed.

D. Discussion Concerning Claims 22-37 and the Cited References

Independent claim 22 calls for a combination of elements comprising “a handle,” “an elongate catheter body,” “a control element defining a distal portion operably connected to the distal portion of the catheter body and a **proximal portion** extending along the **exterior** surface of the catheter body” and “an apparatus, located in spaced relation to the handle body, **adapted to secure the proximal portion of the control element in predetermined relation to the catheter body.**”

1. Statement Under 37 C.F.R. § 1.192(c)(7)

In accordance with the separate patentability requirements of 37 C.F.R. § 1.192(c)(7), applicant respectfully submits that claims 22-37 are patentably distinct from claims 10-13 and 15-21 because claims 22-37 are both novel and non-obvious over claims 10-13 and 15-21. With respect to novelty, independent claim 22 calls for “an

apparatus, located in spaced relation to the handle body, adapted to secure the proximal portion of the control element in predetermined relation to the catheter body," while claims 10-13 and 15-21 do not. Additionally, because the prior art does not suggest modifying the inventions defined by claims 10-13 and 15-21 such that they include the aforementioned "apparatus," claims 22-37 are non-obvious over claims 10-13 and 15-21.

2. The Rejection of Claims 22, 23 and 27-37 Under 35 U.S.C. § 102

The Whayne '279 patent fails teach or suggest a number of elements in the combination defined by independent claim 22. For example, the Examiner has apparently taken the position that structures 26, 36 or 304 in the Whayne '279 patent correspond to the claimed "apparatus ... adapted to secure the proximal portion of the control element in predetermined relation to the catheter body." [Office Action at page 2.] Applicant respectfully submits that this position is without merit.

Referring to Figure 1 of the Whayne '279 patent, structure 26 is a sheath and structure 36 is a gripping surface for the sheath. The catheter tube 12 passes through the sheath 26 and the steering wire 66 is located within the catheter tube. The sheath 26 and gripping surface 36 simply are not used (alone or individually) to secure the proximal portion of the steering wire 66 relative to the catheter tube 12, or any other structural element for that matter.

Turning to Figure 53 of the Whayne '279 patent, structure 304 is also a sheath through which the catheter tube 12 passes. The pull wire 334 passes through the sheath 304, exits through the proximal end of the sheath, and is connected to the stop 336. The pull wire 334 is free to move within the sheath 304 relative to the catheter tube. The sheath 304 simply does not **secure** the proximal portion of the pull wire in predetermined relation to the catheter tube 12, or any other structural element for that matter.

As the Whayne '279 patent fails to teach or suggest each and every element of the combination recited in independent claim 22, applicant respectfully submits that

claims 22, 23 and 27-37 are patentable thereover and that the rejection under 35 U.S.C. § 102 is improper and should be reversed.

2. The Rejection of Claims 24-26 Under 35 U.S.C. § 103

Applicant respectfully submits that the Brennen '006 patent fails to remedy the deficiencies in the Whayne '279 patent described above with respect to independent claim 22. For example, the Brennen '006 patent does not teach or suggest the use of a control element with a *proximal* portion extending along the *exterior* surface of the catheter body. The *proximal section* 14 of the Brennen pull wire 12 is, instead, located *within* the tubular member 10. The Brennen '006 patent also fails to teach or suggest an apparatus, located in spaced relation to the handle 28, that secures the proximal portion of the pull wire 12 to the tubular member 10. To the contrary, the Brennen pull wire 12 is secured to the pivotable lever 34 on the handle 28.

As the Whayne '279 and Brennen '006 patents fail to teach or suggest the respective combinations of elements recited in claims 24-26 (which by definition include the combination of elements recited in independent claim 22), applicant respectfully submits that the rejection of claims 24-26 under 35 U.S.C. § 103 is improper and must be reversed.

IX. CONCLUDING REMARKS

As applicant has shown above, the rejections of claims 10-13 and 15-37 are improper and should be reversed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such

fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

5/16/04
Date

Henricks, Slavin & Holmes LLP
840 Apollo Street, Suite 200
El Segundo, CA 90245
(310) 563-1458
(310) 563-1460 (Facsimile)

Respectfully submitted,

Craig A. Slavin
Reg. No. 35,362
Attorney for Applicant

Appendix

10. A catheter assembly, comprising:
 - a handle including a handle body and a strain relief element;
 - an elongate catheter body defining a distal portion, a proximal portion associated with the handle, and a size and flexibility suitable for insertion into a human body; and
 - a control element defining a distal portion operably connected to the distal portion of the catheter body and a proximal portion extending along the exterior surface of the catheter body and secured to the strain relief element.
11. A catheter assembly as claimed in claim 10, wherein the control element comprises a pull wire.
12. A catheter assembly as claimed in claim 10, wherein the control element defines a distal end, the catheter body defines a distal end, and the distal end of the control element is associated with the distal end of the catheter body.
13. A catheter assembly as claimed in claim 10, wherein the control element is secured to the strain relief element by a substantially tubular member which surrounds respective portions of the strain relief element and the control element.
14. A catheter assembly as claimed in claim 13, wherein the substantially tubular member comprises heat shrink tubing.
15. A catheter assembly as claimed in claim 10, further comprising:
 - a sheath surrounding at least respective portions of the catheter body and control element.

16. A catheter assembly as claimed in claim 10, further comprising:
 - a physiological treatment element carried by the distal portion of the elongate catheter body.
17. A catheter assembly as claimed in claim 16, wherein the physiological treatment element comprises a diagnostic element.
18. A catheter assembly as claimed in claim 16, wherein the physiological treatment element comprises a therapeutic element.
19. A catheter assembly as claimed in claim 16, wherein the physiological treatment element comprises an electrode element.
20. A catheter assembly as claimed in claim 19, wherein the electrode element comprises a porous electrode element.
21. A catheter assembly as claimed in claim 19, wherein the electrode element comprises a flexible electrode element.
22. A catheter assembly, comprising:
 - a handle including a handle body;
 - an elongate catheter body defining a distal portion, a proximal portion associated with the handle, and a size and flexibility suitable for insertion into a human body;
 - a control element defining a distal portion operably connected to the distal portion of the catheter body and a proximal portion extending along the exterior surface of the catheter body; and
 - an apparatus, located in spaced relation to the handle body, adapted to secure the proximal portion of the control element in predetermined relation to the catheter body.

23. A catheter assembly as claimed in claim 22, wherein the handle includes a strain relief element associated with the handle body and the apparatus includes the strain relief element.

24. A catheter assembly as claimed in claim 23, wherein the apparatus further includes a device that secures the proximal portion of the control element to the strain relief element.

25. A catheter assembly as claimed in claim 24, wherein the device comprises an anchoring element.

26. A catheter assembly as claimed in claim 25, wherein the anchoring element comprises a tube.

27. A catheter assembly as claimed in claim 22, wherein the apparatus covers a region of the proximal portion of the control element and a region of the proximal portion of the catheter body.

28. A catheter assembly as claimed in claim 22, wherein the apparatus comprises an anchoring element that secures the proximal portion of the control element to the proximal portion of the catheter body.

29. A catheter assembly as claimed in claim 28, wherein the anchoring element comprises a tube.

30. A catheter assembly as claimed in claim 22, wherein the control element comprises a pull wire.

31. A catheter assembly as claimed in claim 22, further comprising:
a sheath surrounding at least respective portions of the catheter body and control element.

32. A catheter assembly as claimed in claim 22, further comprising:
a physiological treatment element carried by the distal portion of the
elongate catheter body.
33. A catheter assembly as claimed in claim 32, wherein the physiological
treatment element comprises a diagnostic element.
34. A catheter assembly as claimed in claim 32, wherein the physiological
treatment element comprises a therapeutic element.
35. A catheter assembly as claimed in claim 32, wherein the physiological
treatment element comprises an electrode element.
36. A catheter assembly as claimed in claim 35, wherein the electrode element
comprises a porous electrode element.
37. A catheter assembly as claimed in claim 35, wherein the electrode element
comprises a flexible electrode element.